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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,506	09/15/2003	Muhammad Ashraf	AM-101106US	1850

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,506	ASHRAF ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 10-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of February 9, 2007 made to the office action filed November 15, 2006. Claims 1-6 and 10-20 are pending. Claims 1, 4 and 6 are amended and claim 20 is new.

In light of the amendments, the 35 USC 102(e) rejection of claims 1, 2, 4, and 6 as being anticipated by Rubino et al. is withdrawn.

In light of the amendments, the 35 USC 103(a) rejection of claims 3, 5, and 10-19 as being unpatentable by Rubino et al. as applied to claims 1, 2, 4, and 6 and in view of Azrolan et al. is withdrawn. Examiner notes that the heading of the 35 USC 103(a) rejection in the Non-Final rejection filed November 15, 2006 discloses Patel et al. (US 6,248,363 B1) instead of Azrolan et al., but the text is taken from Azrolan et al. and is cited in the PTO-892 instead of Patel et al. Therefore, the correct heading should be "Claims 3, 5, and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubino et. al. (US 2004/0167152 A1) as applied to claims 1, 2, 4, and 6 above, and in view of Azrolan et al. (US 2002/0013335 A1).

The Applicant's arguments of the nonstatutory provisional obviousness-type double patenting rejection of claims 1, 2, and 4-6 as being unpatentable over claims 55,

58-61, 65, and 72-73 of copending Application No. 10/930,487 were found not persuasive.

The Applicant's arguments of the nonstatutory provisional obviousness-type double patenting rejection of claims 1, 2, and 4-6 as being unpatentable over claims 1, 7-8 and 11 of copending Application No. 11/030,685 were found not persuasive.

In light of amendments to the claims a new 35 USC 112 rejection is made below.

Due to the amendment to the claims, and since additional Obvious Double Patenting rejections were not included in the previous office action, it is now being made, and hence is a new Non-final action. Even though new rejections are being made, Examiner will address Applicant's arguments.

Claim Rejections - 35 USC § 112

Claims 1-6 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amount of the water soluble polymer and surfactant state a range from about 1% to about 40%, about 1% to about 8%, about 5%

to about 20%, or about 3% to about 5%. The "about" range is not supported in the specification (see page 3, lines 21-24). Also, the range of about 1% to about 5% of CCI-779 is also not supported by the specification (see page 3, lines 20-21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-6 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azrolan et al. (US 2002/0013335 A1) in view of Haeberlin, et al. (GB 2327611 A)

and in further view of Madhavi et al. (Food Antioxidants: Technological, Toxicological, and Health Perspectives, Decker, 1996).

Azrolan et al. teaches oral formulations of 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations sodium lauryl sulfate, polyvinylpyrrolidone, poloxamer 188, sodium dodecyl sulfate, sodium citrate, and a dry granulation (see page 4, column 1, paragraph 26, lines 10-12, 16-18, 25, column 2, line 1). For suspensions as a free base or pharmacologically acceptable salt hydroxyl-propyl-cellulose is used (see page 4, column 2, paragraph 28, lines 2-6). For sterile powders, polyethylene glycol, water, ethanol, and vegetable oils are used (see page 4, column 2, paragraph 29, lines 2-4 and 10-12). Under ordinary conditions of storage and use, the preparation contains a preservative to prevent the growth of microorganisms (see page 4, paragraph 28, lines 8-10).

In regards to claims 10-12 and 15-17, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), see also MPEP § 2113.

Azrolan et al. does not teach the specific wordage "water soluble polymer" or "pH modifying agent". Additionally, the ranges of the water soluble polymer, surfactant and antioxidant are not disclosed (claims 1, 10, 15, and 20). Azrolan et al. also does not teach the specific antioxidant butylated hydroxyanisole or butylated hydroxytoluene (claims 13 and 18), nor citric acid (claim 20).

Haeberlin, et al. teaches the use of various carboxylic acids to stabilize (i.e. preserve) oral and parenteral formulations of macrolides, preferably a rapamycin (see abstract). The preferred acids include malonic acid, oxalic acid, citric acid, and lactic acid, and a 0.05% to 5% acid concentration range (which encompasses the instant invention citric acid concentration specification) with further disclosure that the preferred amount of acid may be determined by routine experimentation (see page 4, lines 15-26) is taught.

Madhavi et al. teaches that BHA is perhaps the most extensively used antioxidant in food industry (see page 277, section 5.2.2, first paragraph, lines 1-2, for example). The absorption and metabolism of BHA has been studied in rats, rabbits, dogs, monkeys, and humans. BHA was rapidly absorbed from the gastrointestinal tract in rats, rabbits, dogs, and humans, rapidly metabolized and completely excreted (see page 278, toxicological studies, lines 1-4, for example). BHT is another antioxidant used extensively in the food industry and is widely used in combination with other

antioxidants such as BHA, propyl galate and citric acid (antioxidants disclosed on page 4 of the applicant's specification as acceptable antioxidants), see page 283, paragraph three, butylated hydroxytoluene, lines 1-4.

Although sodium citrate, sodium lauryl sulfate, sodium dodecyl sulfate, poloxamer, polyvinylpyrrolidone (PVP), polyethylene glycols, and hydroxyl-propyl-cellulose are not disclosed as water soluble polymers, surfactants, or pH modifying agents, a chemical composition and its properties are inseparable. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In regards to the range of the antioxidant, water soluble polymer and surfactant in the composition, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Since there are no reasons disclosed why the particular range of 0.001% to 3%, about 1% to about 40%, and about 1% to about 8% gives results that produce unexpected results, then the ranges of the antioxidant, water soluble polymer and surfactant are obvious to one skilled in the art to obtain. It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219

(CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

One having ordinary skill in the art at the time the invention was made would have found it obvious and motivated to formulate a composition of Azrolan et al. and the specific antioxidant butylated hydroxyanisole or butylated hydroxytoluene because Madhavi et al. teaches that BHA and BHT are extensively used antioxidants that are rapidly absorbed from the gastrointestinal tract, metabolized and completely excreted in humans (see page 277, section 5.2.2, paragraph 1, lines 1-2 and page 283, paragraph 3, butylated hydroxytoluene, lines 1-4).

One having ordinary skill in the art at the time the invention was made would have found it obvious and motivated to formulate a composition of Azrolan et al. and citric acid because Haeberlin, et al. teaches the use of various carboxylic acids to stabilize (i.e. preserve) oral and parenteral formulations of macrolides, preferably a rapamycin (see abstract). The preferred acids include malonic acid, oxalic acid, citric acid, and lactic acid in the concentration range of 0.05% to 5% (which encompasses the instant invention citric acid concentration specification) and further discloses that the preferred amount of acid may be determined by routine experimentation (see page 4, lines 15-26). Additionally, Azrolan et al. teaches that under ordinary conditions of

storage and use, the preparation contains a preservative to prevent the growth of microorganisms (see page 4, paragraph 28, lines 8-10). Since, CCI-779 is a derivative of rapamycin as well as a macrolide, one of ordinary skill in the art would reasonably expect citric acid to stabilize (i.e. preserve) the composition.

The motivation for a composition comprising PVP and sodium lauryl sulfate or sodium dodecyl sulfate is because Azrolan et. al. teaches that these components are useful for making tablets (see page 4, column 1, paragraph 26, line 10), suspensions (see page 4, column 2, paragraph 28, line 3), and sterile powders (see page 4, column 2, paragraph 29, lines 2-4). It would be beneficial for the applicant's composition to be made in to a tablet, suspension or sterile powder for use as a medicament. In addition, Rubino et al. states that one of skill in the art may readily select other suitable surfactants (see page 2, column 2, paragraph 21, lines 7-8). Thus, a suitable surfactant and water soluble polymer is chosen based on the type of appearance (i.e. powder, suspension, tablet) or potential use that one of ordinary skill in the art wants to make.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 1, 2-6, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55, 58-61, 65, and 72-73 of copending Application No. 10/930,487 in view of Azrolan et al. (US 2002/0013335 A1). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 10/930,487 teaches a composition comprising an amorphous form of rapamycin 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid, comprising: a metal chelator, a pH adjuster, a surfactant, at least

one filler, a binder, a disintegrant, and a lubricant (see claim 55). The pH adjuster comprises citric acid, ascorbic acid, fumaric acid or malic acid (see claims 58-59). The surfactant is selected from a polysorbate, a sorbitan ester, poloxamer, or sodium lauryl sulfate (see claims 60 and 61). The binder comprises providone, hydroxypropylmethylcellulose, carboxymethylcellulose or gelatin (see claim 65). The composition is dry or wet granulated (see claims 72 and 73), and can be in the form of a tablet (see claim 74).

The U.S. Application 10/930,487 does not teach the specific wordage "water soluble polymer" or "antioxidant", wherein the antioxidant is from 0.001% to 3% (wt/wt). Additionally, the ranges of the water soluble polymer and surfactant are not disclosed, or the use of polyvinylpyrrolidone.

Azrolan et al. teaches oral formulations of 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations sodium lauryl sulfate, polyvinylpyrrolidone, poloxamer 188, sodium dodecyl sulfate, and wet or dry granulation (see page 4, column 1, paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). For suspensions as a free base or pharmacologically acceptable salt hydroxyl-propyl-cellulose is used (see page 4, column 2, paragraph 28, lines 2-6). For sterile aqueous solutions or dispersions and sterile powders, polyethylene glycol, water, ethanol, and vegetable oils are used (see page 4, column 2, paragraph 29, lines 2-4 and 10-12).

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising a water soluble polymer and an antioxidant according to 10/930,487 because hydroxypropylmethylcellulose (see claim 72) is a water soluble polymer and ascorbic acid (see claim 58) is an antioxidant. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In regards to the range of the antioxidant, water soluble polymer and surfactant in the composition, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Since there are no reasons disclosed why the particular range of 0.001% to 3%, about 1% to about 40%, and about 1% to about 8% gives results that produce unexpected results, then the ranges of the antioxidant, water soluble polymer and surfactant are obvious to one skilled in the art to obtain.

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising polyvinylpyrrolidone (PVP) because Azrolan et al. teaches a composition comprising 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations polyvinylpyrrolidone (see page 4, column 1,

paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). Thus, the specific water soluble polymer, PVP, has been taught in combination with the Applicant's compound in a solid preparation.

(2) Claims 1, 2-6, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-8 and 11 of copending Application No. 11/030,685 in view of Azrolan et al. (US 2002/0013335 A1). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 11/030,685 teaches a composition comprising micronized CCI-779, surfactant, filler/binder, disintegrant (see claims 1 and 7), one or more antioxidants, a chelating agent, and/or a pH modifier (see claim 11). The surfactant is sodium lauryl sulfate (see claim 8). An oral CCI-779 dosing unit comprises citric acid at 0.08% w/w, BHT at 0.05% w/w, BHA at 0.022% w/w (see claim 23), and 2% w/w hydroxypropylmethylcellulose (see claim 26). The dosing unit is selected from the group consisting of a tablet and a capsule (see claim 27).

The U.S. Application 11/030,685 does not teach the specific wordage "water soluble polymer" or a composition comprising a granulation. Additionally, the specific water soluble polymer, polyvinylpyrrolidone (PVP) and its amounts are not disclosed.

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising a water soluble polymer and a composition comprising a granulation according to 11/030,685 because hydroxypropylmethylcellulose (see claim 26) is a water soluble polymer and the composition is in granular form due to formation of a tablet (see claim 27). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising polyvinylpyrrolidone (PVP) because Azrolan et al. teaches a composition comprising 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations polyvinylpyrrolidone (see page 4, column 1, paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). Thus, the specific water

soluble polymer, PVP, has been taught in combination with the Applicant's compound in a solid preparation.

In regards to the range of the PVP, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Additionally, the water soluble polymer, hydroxypropylmethylcellulose is in the composition in about 2% w/w (see claim 26). Thus, it would be obvious to comprise the composition with the same amounts of a different water soluble polymer. Since there are no reasons disclosed why the particular range of about 5% to about 20% wt/wt gives results that produce unexpected results, then the ranges of the water soluble polymer are obvious to one skilled in the art to obtain.

(3) Claims 1, 2, 4, and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 and 19 of copending Application No. 10/626,943. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 10/626,943 teaches a parenteral formulation (see claim 12) which comprises an antioxidant, propylene glycol (see claim 15), citric acid (see claim

14), a surfactant (see claim 12), ethoxylated vegetable oil, and polyoxyethylene-polyoxypropylene block copolymers (see claim 16). The antioxidant comprises from about 0.0005 to 0.5% w/v of the formulation.

The U.S. Application 10/626,943 discloses range of the antibiotic is w/v, whereas the applicant discloses the antibiotic range in wt/wt. The different measurements are viewed as the same to one ordinarily skilled in the art. The w/v measurements are taken in regards to the co-solvent concentrate, which is water (see claim 15). Since water has a density of 1 g/mL, and the weight of the applicant's composition is taken as a whole (i.e. 1), then the measurements are virtually the same.

The U.S. Application 11/030,685 does not teach the specific wordage "water soluble polymer" or a composition comprising a solid granulation. Additionally, the ranges of the water soluble polymer and surfactant are not disclosed.

Although citric acid is disclosed as an antibiotic and polyethylene glycol is disclosed as a dilute solvent, a chemical composition and its properties are inseparable. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In regards to the range of the water soluble polymer and surfactant in the composition, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Since there are no reasons disclosed why the particular range of about 1% to about 40%, and about 1% to about 8% gives results that produce unexpected results, then the ranges of the antioxidant, water soluble polymer and surfactant are obvious to one skilled in the art to obtain.

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising a solid granulation because it is a species of the genus parenteral formulation (see claim 12). In other words, a parenteral formulation can be in a solid granulation and since there are no reasons disclosed why the solid granulation form gives results that produce unexpected results, then the the solid granulation form is obvious to one skilled in the art to obtain.

Response to Arguments

Double Patenting

Applicant's arguments filed February 9, 2007 have been fully considered but they are not persuasive.

(1) Claims 1, 2, and 4-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55, 58-61, 65, and 72-73 of copending Application No. 10/930,487.

The Applicant argues that a formulation drawn to formulations containing amorphous CCI-779 does not render obvious the Applicant's formulation of CCI-779 with specified excipients.

The claimed and prior art compositions are substantially identical and a prima facie case or obviousness has been established, in the previous office action and above, thus the Applicant's arguments of the were found not persuasive.

The Applicant's claims are drawn to a composition only limited to the form of a granulation, and in the recent amendement to a solid. The application No. 10/930,487 discloses a dry granulated composition (see claims 72 and 73) in the form of a tablet (see claim 74). Hence, a solid granulated composition is taught. The Applicant's specific excipients are also disclosed and discussed in the previous office action and repeated above in the new office action.

(2) Claims 1, 2, and 4-6 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-8 and 11 of copending Application No. 11/030,685.

The Applicant argues that a formulation drawn to formulations containing micronized CCI-779 does not render obvious the Applicant's formulation of non-icronized CCI-779 with specified excipients.

The claimed and prior art compositions are substantially identical and a prima facie case or obviousness has been established, in the previous office action and above, thus the Applicant's arguments of the were found not persuasive.

The Applicant's claims are drawn to a composition only limited to the form of a granulation, and in the recent amendement to a solid. The application No. 11/030,685 discloses a tabulated composition (see claim 27). Hence, one skilled in the art can make the tablet in a granular form. Therefore, a solid granulated composition is taught. The Applicant's specific excipients are also disclosed and discussed in the previous office action and repeated above in the new office action.

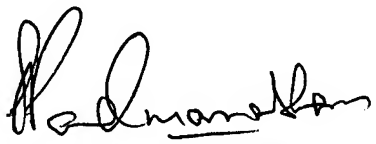
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC



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